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March 21, 2023

The Honorable Gregory B. Williams
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801-3555

VIA ELECTRONIC FILING

Re: *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*
C.A. No. 21-1015 (GBW)

Dear Judge Williams:

Counter-Plaintiff/Defendant Sarepta Therapeutics, Inc. (“Sarepta”) respectfully requests leave to amend its answer to join the patent owner, The University of Western Australia (“UWA”), as a counter-plaintiff on Sarepta’s infringement counterclaims. UWA consents to joinder as a counter-plaintiff. Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) and Counter-Defendant NS Pharma, Inc. (collectively, “NS”) oppose this motion. The parties have had extensive discussions about joining UWA, and NS has advised us that its opposition is based solely on resolving certain issues relating to discovery.

Attached to the motion accompanying this letter are Sarepta’s First Amended Answer, Defenses, and Counterclaims (“First Amended Answer”) with all exhibits (Ex. 1), and a blackline comparison (Ex. 2) to Sarepta’s original Answer, Defenses, and Counterclaims (D.I. 89). Joinder of UWA as a counter-plaintiff is proper at least under Fed. R. Civ. P. 19. Sarepta’s request is timely under the Scheduling Order (*see* D.I. 143, ¶ 2) and does not prejudice NS. The motion is not futile or made in bad faith or with a dilatory motive. Thus, Sarepta’s motion should be granted.

I. Joinder of UWA as a Counter-Plaintiff Is Appropriate

NS’s Second Amended Complaint asserted against Sarepta a claim for declaratory judgment of invalidity of U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827 (collectively, “the UWA Patents”). (D.I. 86, Claim II.) Sarepta’s answer asserted counterclaims against NS for infringement of the UWA Patents. (D.I. 89, Counterclaims I-III.) The UWA Patents are assigned to UWA. Through a license agreement with UWA, Sarepta holds the exclusive rights to the UWA Patents for the treatment of muscular dystrophies and has the right to enforce the UWA Patents. (D.I. 89, ¶ 2.)

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Joinder of UWA in this action is appropriate under Fed. R. Civ. P. 19. As the assignee and licensor of the UWA Patents, UWA has an ownership interest in the UWA Patents that are the subject of NS's invalidity declaratory judgement claim and Sarepta's infringement counterclaims against NS. UWA's ability to protect its ownership interest would be impaired if it is not joined as a counter-plaintiff. Further, UWA has the statutory right to bring an action for infringement of the UWA Patents. 35 U.S.C. § 281 ("A patentee shall have remedy by civil action for infringement of his patent."). Jurisdiction and venue for UWA's claims against NS are proper since UWA has consented to joinder.

The Federal Circuit has held that Fed. R. Civ. P. 19 "direct[s] courts to join patentees along with licensees who otherwise have standing . . . regardless of whether joinder is prompted by the patentee or the licensee. In either case, the patentee must be joined, if feasible, when it is a necessary party." *Lone Star Silicon Innovations L.L.C. v. Nanya Tech. Corp.*, 925 F.3d 1225, 1236-37 (Fed. Cir. 2019). Here, Sarepta, the exclusive licensee, moves to join UWA, the patentee. Joinder is feasible at least because UWA has consented to voluntarily join this action. Sarepta, as an exclusive licensee of the UWA Patents, has Article III standing to enforce its exclusionary rights against NS. *See id.* at 1235-36 (exclusive licensee satisfied Article III standing). Joinder of UWA would "further the purposes of [Fed. R. Civ. P. 19]" by allowing Sarepta to "vindicate [its] rights." *Id.* at 1237. Thus, joinder of UWA as a counter-plaintiff in this action is appropriate.

Joinder of UWA is also appropriate under Fed. R. Civ. P. 21. The Court "may at any time, on just terms, add or drop a party." *Id.*; *see also Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1385 (Fed. Cir. 2015) (acknowledging the judicial practice of joining a patentee under Rule 21). Thus, if Sarepta lacks statutory standing to enforce the UWA Patents without patent owner UWA, the Federal Circuit has "consistently said that the cure for this defect is to join the patent owner and not to dismiss the case." *Lone Star*, 925 F.3d at 1238.

II. Leave to Amend Should Be Freely Granted

Leave to amend the pleadings as requested by Sarepta is proper. The Court "should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The Third Circuit follows a "liberal" approach to the amendment of pleadings to ensure that "a particular claim will be decided on the merits rather than on the technicalities." *Dole v. Alco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990). Accordingly, leave to amend should be granted absent undue delay, prejudice, bad faith, dilatory motive, or futility. *See Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006). None of these factors exist here.

a. Sarepta's Motion Is Timely and Does Not Prejudice NS

This motion is timely. It is made before the March 23, 2023 deadline for amending pleadings and joining other parties set forth in the Scheduling Order (D.I. 143, ¶ 2). *See Invensas Corp. v. Renesas Elecs. Corp.*, No. 11-448-GMS-CJB, 2013 WL 1776112, at *4 (D. Del. Apr. 24, 2013) ("The fact that the Motion was filed within this deadline . . . strongly supports a conclusion that the amendment was not untimely filed"); *see also Greatbatch Ltd. v. AVX Corp.*, No. 13-723-LPS, 2014 WL 491683, at *1-2 (D. Del. Feb. 4, 2014) (granting motion to amend filed before the deadline and at an early stage). Further, this motion comes early in the litigation—there have been no depositions taken to date, the parties have exchanged only initial infringement and invalidity

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contentions, fact discovery closes on July 27, 2023, and trial is scheduled to begin on May 13, 2024. The current request therefore is unlikely to affect any currently scheduled dates.

For the same reasons, joinder of UWA would not prejudice NS. When, as here, a motion is timely filed, “there can be no unfair prejudice to defendant.” *Butamax Advanced Biofuels L.L.C. v. Gevo, Inc.*, No. 11-54-SLR, 2012 WL 2365905, at *2 (D. Del. June 21, 2012). Moreover, UWA has been cooperating in discovery in this action and, for example, has already facilitated the production through Sarepta of its laboratory notebooks relating to the experimental work leading to the UWA Patents. Additionally, the proposed amendments do not raise any additional products or patents, and no duplicate discovery efforts should be required.

In declining to consent to joinder, NS expressed concern that UWA would not meet its discovery obligations after joinder. No basis exists for this concern. As noted, UWA has already facilitated the production of its laboratory notebooks. Further, once UWA is joined as a party, NS can serve discovery requests directly on UWA. Fact discovery remains open until July 27, 2023; thus, there is ample time in the schedule for NS to serve additional discovery requests and UWA intends to fully comply with its discovery obligations after it joins the case. But UWA is joining the case solely to address any perceived standing deficiency in connection with Sarepta’s infringement counterclaims, and its discovery obligations should be reasonably commensurate with that limited involvement in the case.

b. Amendment Would Not Be Futile

As the proposed amended pleading makes clear, there is sound legal basis for Sarepta and UWA’s infringement counterclaims against NS, and jurisdiction and venue are proper in this District. UWA and Sarepta have adequately pled their allegations that NS has infringed the UWA patents. The proposed amendment would not be futile. NS has not raised futility in the parties’ discussions.

c. Sarepta’s Motion Is Not Made in Bad Faith or with Dilatory Motive

After asserting counterclaims against NS for infringement of the UWA Patents, Sarepta attempted in good faith to work out a joint stipulation that would resolve any dispute over Sarepta’s statutory standing to maintain those counterclaims. Sarepta sent NS a proposed stipulation on statutory standing on December 20, 2022, but after waiting for weeks, NS rejected that proposal during a meet and confer conference on February 15, 2023. Sarepta then obtained UWA’s consent to join the case on March 2, 2023. Sarepta is seeking leave to amend promptly after meeting and conferring with counsel for NS on March 9 and March 17, 2023. NS has not argued bad faith or dilatory motive in the parties’ discussions.

Sarepta’s motion is timely, not prejudicial or futile, and made in good faith. For these reasons, Sarepta respectfully requests leave to file the proposed First Amended Answer reflecting the joinder of UWA as a counter-plaintiff on Sarepta’s infringement counterclaims against NS.

III. Conclusion

Sarepta respectfully requests that the Court grant its motion and allow Sarepta to file its First Amended Answer joining UWA as a counter-plaintiff.

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Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via electronic mail)